



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/436,513	11/09/1999	JOHN BRYAN JONES	3290.007US1	6754

23639 7590 06/03/2002

MCCUTCHEN, DOYLE, BROWN & ENERSEN LLP
THREE EMBARCADERO, SUITE 1800
SAN FRANCISCO, CA 94111-4067

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
----------	--------------

1652

DATE MAILED: 06/03/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/436,513	JONES ET AL.
	Examiner	Art Unit
	Charles L. Patterson, Jr.	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 April 2002 and 15 April 2002.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11, 13, 21-57, 59, 61 and 62 is/are pending in the application.
 4a) Of the above claim(s) 21-50 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-11, 13, 51-57, 59, 61 and 62 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 25 July 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

The inventorship change meets the requirements of 37 CFR 1/48 and has been approved and entered.

Claims 21-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

It is noted that the substitute specification submitted 7/25/01 does not contain Figures 7A, 7B and 8. These figures are still mentioned in the specification and must be included in the application absent a convincing argument not to and elimination of any mention in the specification. Therefore these figures have not been resubmitted to the draftsman for approval. It is noted that correction of the drawings may not now be held in abeyance (37 CFR 1.85).

Claims 1-11, 13, 51-57, 59 and 61-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Bacillus lenthus subtilisin* N62C-a, N62C-d, N62C-e, N62C-f (R isomer only), N62C-h, N62C-i (R isomer only), S166C-d (S isomer only), S166C-h (S isomer only), S166C-I (S isomer only), L217C-a, L217C-b, L217C-d, L217C-e, L217C-f and L217C-i, does not reasonably provide enablement for the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Art Unit: 1652

Applicants argue that the claims should not be limited to the enablement outlined above but should be enabled for the full scope of the instant claims. The instant specification teaches that the amidase and/or esterase activity of the strains listed *supra* are above the wild type but applicants argue that the ratio of the two activities is important without giving any discussion or reason. In addition, there is no argument as to why the scope of the claims should be enlarged beyond *Bacillus lentus subtilisin*.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 13, 51-57, 59 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berglund, et al. (A or C2). This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. The previous rejections over Davis, et al. and De Santis, et al. have been dropped in view of the Katz declaration submitted.

Applicants argue that because two references do not use chiral substituents, the instant claims should be allowable over them. The references teach the modification of an enzyme by adding a cysteine and then modifying the cysteine molecule by changing the thiol group with methanethiosulfonate reagents. It is well known that some chemical compounds are chiral and some are not and whether this limitation should make a difference in the allowability of the instant claims is a fact based matter. Berglund, et al. (C2)

Art Unit: 1652

states in the first paragraph that "site-directed mutation...offers virtually unlimited possibilities for creating new structural environments at any enzyme location", which it is maintained envisions both chiral and non-chiral compounds. It is maintained that whether a particular mutation is patentable over the prior art depends upon whether it has some useful property and all chiral substituents have not been shown to have such a useful property (see 35 USC 112 first paragraph rejection, *supra*).

It would have been obvious to one of ordinary skill in the art to modify enzymes as taught in the instant references and it would have been further obvious to use both chiral and non-chiral compounds in view of the well known fact that there both type compounds exist and in view of the statement mentioned *supra* in Berglung et al. (C2). The motivation would have been to produce mutant enzymes and to assay their properties.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
May 31, 2002